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NATIONAL COMMITTEE FOR QUALITY HEALTH CARE'S ANNUAL CONFERENCE ON

Breakthroughs in Bio-Medical Technology: Their Impact on Quality Healthcare

November 17, 2000

The Ritz Carlton
Washington, DC

National Committee for Quality Health Care

CONFERENCE REPORT

Washington, DC
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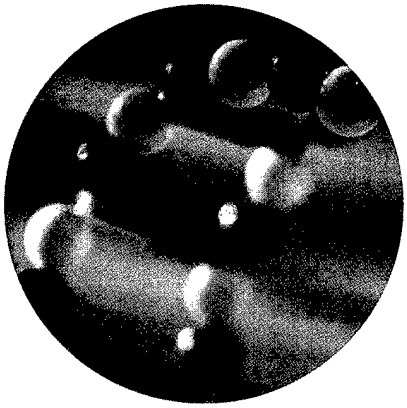

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

<None>Bio-medical technology breakthroughs are changing the face of health care. To promote further understanding of this phenomenon, the National Committee for Quality Health Care (NCQHC) brought together a variety of experts for a one-day seminar on November 17, 2000. Co-sponsors for the event included Abbott Laboratories, AMGEN, Batelle, Hoffman-La Roche, Inc., Johnson & Johnson Healthcare Systems, Inc., *Modern Healthcare*, Mallinckrodt, Inc., Sodexho Marriott Services, Inc., and the Telemedicine Advanced Technology Research Center of the Army (TATRC).

This report provides a detailed summary of the presentations and discussion that took place.

Overview of the Future of Medical Technology

William M. Dwyer, MBA, divisional vice president of strategic marketing in Abbott Laboratories HealthSystems Division as well as a current board member and past board chair of NCQHC, provided his views on the future of medical technology. He sees a number of forces that together will build on each other, causing a medical revolution that will sweep around the world:

- ***Force #1: Advances in Genetics***

  The Human Genome Project (HGP) will have profound implications on the nation's health care system. It will first target the three to four percent of genes that, if inherited, cause a disorder. The ultimate goal is to replace these genes and thus avert disease altogether. A variety of specific advances will help to reach this goal, including gene therapies that can sprout the growth of new blood vessels, gene "chips" that provide unique DNA profiles, and anti-aging treatments.

- ***Force #2: Advances in Cloning***

  Cloning of adult mammals is one of the most important breakthroughs over the last century. Mr. Dwyer believes that the technology will continue to advance at a rapid pace.

- ***Force #3: Combinatorial Chemistry and the Creation of Novel Drugs/Vaccines***

  Mr. Dwyer expects rapid innovation in the creation of novel drugs, driven largely by the findings of HGP and the results of a new process for discovering drugs—combinatorial chemistry. This approach has dramatically increased the speed and scope of drug discovery while simultaneously reducing its costs.

- ***Force #4: Transplants and Implants***

  Tissue re-engineering will be the wave of the future for transplants and implants.

- ***Force #5: Information Technology***

  Huge advances in telemedicine should continue, including some driven by bioelectronic computers that use complex combinatorial analysis and pattern recognition.

- ***Force #6: Complementary Medicine and Faith Healing***

  In the midst of this high-technology revolution, Mr. Dwyer sees a more prominent role for complementary medicine and for faith and spirituality.

Mr. Dwyer concluded his presentation with predictions for the next 100 years, including in the near term the discovery of cures for many cancers, and in the long term a life expectancy that approaches 200 years.

The Human Genome Project and Its Impact on Medicine

Francis S. Collins, MD, PhD, director of the National Human Genome Research Institute of the National Institutes of Health (NIH), provided a more detailed description of HGP and its implications for the future of medicine. A complete working draft of the human genome was completed in June 2000. Interestingly, the complete genome consists of roughly 40,000 genes, only 40 to 50 percent of the 80,000 to 100,000 genes that many researchers expected to find.

The completion of the sequencing of the human genome marks the end of the beginning phase of the effort. The bulk of the work during the current phase centers around studying variations in human genetics. Finding these important variations requires the building of a catalogue that documents each of approximately 10,000,000 "spelling errors" (known as single nucleotide polymorphisms or SNPs) within human DNA. Then researchers must check the errors one at a time to determine if they are significant. This effort is already beginning to pay dividends. Within the past two years, approximately three dozen disease-causing genes have been identified. Similar discoveries for many other diseases should occur within the next few years. Dr. Collins expects that completing the effort to understand genetic variations will take 10 to 20 years.

Once SNPs that are associated with specific diseases have been identified, private and public sector organizations can work to develop both diagnostic tools to determine who is at risk and new, more effective drugs, therapies, or other interventions to prevent and/or treat the disease. He laid out a three-pronged approach to the process:

- Development of diagnostic tools to determine who is at risk, and preventive medicines or pharmacogenomics to prevent or treat the disease.
- Development of gene therapies that work to correct the gene itself.
- Understanding of the basic biological defect that causes the variation, followed by the development of drug therapy to correct this defect.

Another integral aspect of HGP involves examining the ethical, social, and legal implications of genetics. Dr. Collins laid out six critical questions to be answered:

- Will effective legislative solutions to genetic discrimination be found?
- Will we successfully shepherd new genetic tests from research into clinical practice? Who will decide what tests are used (e.g., the Food and Drug Administration, the marketplace, clinical guidelines)?
- Can health care providers and the public become genetically "literate" in time?
- Will the benefits of advances in genetics only be available to a privileged few?
- Will we arrive at a consensus about the limits of genetic technology for trait enhancement?
- Will we succumb to genetic determinism (i.e., the belief that genetics causes everything)?

Dr. Collins concluded his presentation with predictions for the next 30 years, including the development of predictive genetic tests for 10 conditions (along with interventional and/or gene-based therapies for a few of these) within 10 years, gene-based designer drugs for many disorders and precisely targeted cancer therapies within 20 years, and comprehensive, genomics-based health care within 30 years.

Breakthrough Technologies for the New Millennium

Much of the remainder of the conference focused on how public and private organizations have been developing products and services based on advances in genetics and other sciences.

A View from the Pharmaceutical Industry

George Morstyn, MD, senior vice president for development and chief medical officer at AMGEN, offered the perspective of the pharmaceutical industry. He believes that the pharmaceutical industry is in need of a new approach to drug development. To support this view, he highlighted statistics that demonstrate the remote chance that research will result in a new drug reaching the marketplace, let alone becoming commercially successful.

Dr. Morstyn believes that biotechnology can be an integral part of this new approach. He is particularly optimistic about the ability of pharmacogenomics to solve some of the challenges facing the industry. In addition, genetics can help to transform the industry, allowing for the prediction of disease and targeted therapies based on the specific genetic make-up of an individual. Universal blockbuster drugs that treat an entire class of patients will give way to "minibusters" developed with the aid of pharmacogenomics (an approach that should keep development costs relatively low).

AMGEN's role in this revolution will revolve around protein engineering, molecular biology, and cellular biology, which are at the core of AMGEN's competencies. Protein modification, in particular, has provided new opportunities to take existing drugs and modify them.

A View from the Provider Industry

Edward Eckenhoff, president and CEO of the National Rehabilitation Hospital (NRH) in Washington, DC, offered his views on how bio-medical technology is leading to breakthroughs in the provider industry, particularly with respect to rehabilitation. He sees exciting new developments occurring today for the approximately 48,000,000 people in the United States who are disabled. New technologies are making everyday life easier for these individuals.

Mr. Eckenhoff laid out six themes related to technology for individuals with disabilities.

- Theme #1: Robots find a home in rehabilitation.
- Theme #2: Rehabilitation is going wireless (along with everything else).
- Theme #3: Telehealth technologies have come to rehabilitation.
- Theme #4: Rehabilitation and independent living find support in e-health.
- Theme #5: Composite materials are showing up in rehabilitation products.
- Theme #6: Functional electrical stimulation (FES) makes it into clinical practice.

Looking ahead, Mr. Eckenhoff sees great promise in technologies being developed by the National Aeronautics and Space Administration (NASA), including virtual reality, computer modeling techniques, and human interface design. Using his crystal ball, he also envisions a day in which heads-up displays and wearable computers serve to enhance reality while EEG processing may provide output from people who are "locked in".

A View from NASA

Arnauld E. Nicogossian, MD, chief health and medical officer for NASA, reviewed how breakthroughs in biomedical technology at NASA are having an impact on the quality of health care, both in outer space and on earth. NASA's primary goal with respect to health care is to maximize the safety, health, and productivity of the agency's workforce, taking into account the unique health care requirements created by space travel. NASA missions are often characterized by exposure to radiation, extended periods of isolation, living in microgravity, and rapid re-entry into the earth's atmosphere. The human body experiences numerous changes during a mission, including neurovestibular disturbance, cardiac deconditioning, decreased immune function, variations in the endocrine (or nervous) system, muscle atrophy, and loss of bone mass.

NASA maintains the health, safety, and productivity of its crews in space through stringent selection and training and the design of state-of-the-art aircraft. The agency provides a variety of health care services to its crews before, during, and after flights. Looking ahead, time, distance, and microgravity will create a new set of requirements for future health care systems, which need to be autonomous, minimally invasive, compact and portable, human-centered, and self-diagnosing/self-repairing. Cutting-edge technologies hold the key to meeting these future requirements. They range in sophistication from being dependent upon humans to being complex, autonomous, self-replicating, and self-repairing systems. Dr. Nicogossian highlighted a number of these technologies, including biologically-inspired technology, medical informatics, advanced human-machine interfaces, immersive environment technologies, noninvasive procedures, and advanced imaging technologies. Many of these technologies have applications on earth.

The multipurpose international space station (ISS) is the next platform for NASA to study how people can live more productively and safely in space. The ISS will allow NASA to learn to sense the environment to avoid problems or emergencies. Findings from the ISS should have relevance on Earth, especially with respect to learning how to help the elderly, who are often home bound, remain healthy and productive.

A View from the Military

Gary Gilbert, PhD, special assistant for information sciences at the Telemedicine Advanced Technology Research Center (TATRC) of the Army Medical Research and Materiel Command, highlighted the role of telemedicine and medical informatics in the US military. Perhaps the best recent example of the Army's use of telemedicine and informatics came in support of operations in Bosnia. The functional/technical capabilities deployed include the following: telemedicine imagery, filmless teleradiology, digital CT scanner and ultrasound, telesurgical monitoring, hospital information systems, and field medical and patient management information systems.

One of the critical issues facing the military with respect to telemedicine is whether to use real-time or "store-and-forward" modalities. The appropriate choice will depend upon the requirements and capabilities at the delivery site. In Bosnia, real-time capability was available for radiology (e.g., real-time ultrasound), distance learning

(e.g., grand rounds from major academic medical centers), and telesurgical applications. The "store-and-forward" approach was utilized by the Navy, since real-time videoconferencing was found to take up too much bandwidth. In some instances, both real-time and store-and-forward approaches were used.

In today's post-Bosnia era, Dr. Gilbert sees a role for telemedicine in the full continuum of military operations, including times of war, domestic emergencies (e.g., hurricane relief), and peacetime operations. He envisions an expanded definition of telemedicine that utilizes the technology around the world for all three types of activities. Dr. Gilbert provided examples of some of these types of projects, including special medical command control and communications, devices for patient monitoring and transmission to personal computers, high-capacity medical records that rely on voice recognition technology, laser image displays that show information without obstructing vision, special operations handbooks supported by guidelines, and a global grid telemedicine system that provides remote military health care providers with access to US-based medical centers.

Dr. Gilbert believes the future of telemedicine and informatics involves giving physicians a "wireless medical enterprise" that will allow better care management at the point of care. Through use of hand-held devices and very small computers, physicians will be able to access a patient's computerized medical record, research support, administrative support, and evidence-based guidelines. They will also be able to send and receive images. To make this vision a reality, the Army is developing a "telemedicine reference architecture" that integrates different interactive components through hardware and software that work together in an open platform.

Health Care After the Information Age: The Bio-Intelligence Age

Richard Satava, MD, FACS, a professor of surgery at the Yale University School of Medicine, closed the conference by describing what he sees as the next era in health care—the "Bio-Intelligence Age." Dr. Satava believes that the next frontier in medicine will bring together research findings from the biological, physical, and information sciences. It will be based on a detailed understanding of biologic and physical processes, supported by a whole host of smaller, cheaper, ubiquitous devices that use less power and are transparent to the user because they have local intelligence. The world will become "smarter," as networking provides for distributed or embedded intelligence that enables interaction between systems without human intervention.

The Bio-Intelligence Age will revolutionize medicine. Dr. Satava highlighted the "five P's" that will characterize this era: predictive medicine, based on genetics; preventive medicine through proactive interventions; point-of-care medicine in the home and workplace; parametric medicine, where multiple parameters, over time, are referenced to a patient's own baseline and compared to a standard model; and personalized medicine, with individualized treatments.

To give a sense for the tremendous opportunities that this new era will create, Dr. Satava highlighted a handful of Bio-Intelligence applications currently under development, including the placement of transmitters on bumble bees

to identify and transmit the location of biologic agents; use of electrodes that record motion in cockroaches, with the ultimate goal of implanting electrodes that allow researchers to direct the bugs to crawl under buildings to identify survivors of natural and manmade disasters; microsurgical applications that allow operations on insects and even smaller creatures; implantable drug-delivery systems placed on chips the size of a dime; biomaterials that are ten times stronger and one-seventh the weight of titanium; and production of synthetic organs through tissue engineering.

Going forward, the most important application of Bio-Intelligence is the creation of a Holographic Medical Equivalent Representation (HoloMER)TM or "virtual human." Through computerized tomography (CT) or magnetic resonance imaging (MRI) technologies, physicians will one day be able to take a complete three-dimensional image of a human. Multiple scans will provide greater detail in particular areas. The image will also contain the patient's medical records, vital signs, and laboratory data—each of which will be available simply by "clicking" on an organ. These three-dimensional images or holomers will assist in diagnosing and treating a patient through technologies such as non-invasive, "virtual" colonoscopies and endoscopies. Physicians will be able to "practice" difficult surgeries on images identical to the patient. These holomers could one day function as human "surrogates" that allow physicians to "predict" the impact of an intervention on a particular patient before actually using it.

On a cautionary note, Dr. Satava warned that the technological capabilities that he believes are possible will raise moral and ethical issues. For example:

- Should we do research in areas that we may not be able to control?
- Will prolonging life through technology result in more disease in the overall population?
- Can we change medicine from treatment to prevention of disease?
- Will technology change humans into a combination of man and machine?
- How will we decide who gets the technology, especially in third-world nations?

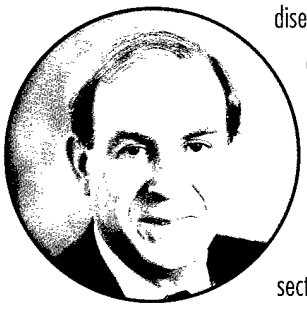
To deal with these issues, Dr. Satava called on the industry to place appropriate limits to ensure that these technologies are applied with compassion for the benefit of mankind.

INTRODUCTION

Bio-medical technology breakthroughs are changing the face of health care. Space exploration, defense systems, pharmaceutical innovations, the human genome project, and pioneering information technologies are all contributing to a vast array of new opportunities to deliver high quality, cost-effective health care to a broader patient population. To promote further understanding of this phenomenon, the National Committee for Quality Health Care (NCQHC) brought together a variety of experts in the field for a one-day seminar. This session, entitled *Breakthroughs in Bio-Medical Technologies: Their Impact on Quality Health Care*, was held on November 17, 2000, at The Ritz-Carlton Hotel in Washington, DC. Charles S. Lauer, corporate vice president of *Modern Healthcare*, served as moderator of the event.

Catherine McDermott, president and chief executive officer (CEO) of NCQHC, began the day by highlighting the very exciting and dynamic nature of the field of bio-medical technology, noting that virtually every day new products and services are being introduced that have the potential for improving the quality of health care.

Samuel Nussbaum, MD, executive vice president of BJC Health System in St. Louis, Missouri, and chairman of the board of NCQHC, reiterated this view by noting that advances in biology will one day lead to the use of genetic interventions that could prevent many illnesses, in some cases eliminating the need to treat disease. But Dr. Nussbaum cautioned that with these advances come ethical issues that must be considered. For example, the past 25 years have brought tremendous advances in imaging (e.g., through magnetic resonance imaging or MRI) and the ability to conduct bone marrow transplants. Yet today 60 to 75 percent of all MRIs are unnecessary, while expensive bone marrow transplants are used even though they appear to provide little if any clinical benefit. Advances in genetic engineering are leading to the formation of many new companies and the reshaping of entire sectors of the world economy. Some of these discoveries are creating tremendous controversy, as witnessed by many Europeans' distrust of genetically modified foods. Recent surveys suggest that six in 10 Americans would like to be genetically profiled. Honoring these wishes will bring major new responsibilities to the industry, such as creating the need for major initiatives to train providers on the implications of these genetic profiles for patients.

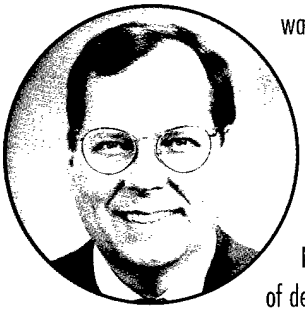


To shed light on these and other related issues, the NCQHC meeting offered a unique opportunity to learn from some of the best minds in science and biology. This report provides a detailed summary of the presentations and discussion that took place at this seminar. It is organized into four chapters. The first, *Overview of the Future of Medical Technology*, takes a broad look at the technological advances that are currently being researched and

developed in the field of health care. The second, *The Human Genome Project and Its Impact on the Future of Medicine*, provides a detailed review of the current status and future implications of the Human Genome Project, a government-funded effort to map the entire human genome and to identify disease-causing variations in it. The third, *Breakthrough Technologies for the New Millennium*, profiles the efforts of various constituencies, most notably the pharmaceutical industry, the provider community, and the federal government (including the space program and the military) to develop exciting new technologies that take advantage of research findings related to the human genome and other important areas. Finally, the fourth chapter *Health Care After the Information Age: The Bio-Intelligence Age*, speculates on what comes next by highlighting the tremendous opportunities being created in the emerging field of bio-intelligence.

CHAPTER I:
OVERVIEW OF THE FUTURE OF MEDICAL TECHNOLOGY

Mr. Lauer began the session by introducing William M. Dwyer, MBA, divisional vice president of strategic marketing in Abbott Laboratories HealthSystems Division as well as a current board member and past board chair of NCQHC. Mr. Dwyer provided his views on the future of medical technology. Much of his presentation, which was based upon extensive research, has been published in Abbott's *Technology Futures Report*™.



Prospects for Eradicating Disease

Mr. Dwyer envisions a future in which some major diseases will be eradicated; possibly including asthma, various cancers, heart disease, and bacterial-induced chronic diseases. Thanks to new pharmaceuticals, new surgical techniques, as well as other technological advances, the leading causes of death for the last 50 years—heart disease, cancer, and stroke—will not be the leading causes of death 25 or 50 years from now. New technologies, including "programmed cell death" through the turning on and off of enzymes, personalized cancer vaccines, and other innovations could help to eradicate cancer. And a variety of new approaches could spell the end of many traditional heart diseases within the next half century; these include advances in surgical techniques and transplants, the ability to correct genetic errors, the use of artificial and
animal parts, and the development of new drugs.

Mr. Dwyer sees a number of forces that together will build on each other, causing a medical revolution that will sweep around the world:

- Advances in genetics, driven by the final completion of the Human Genome Project by 2003.
- Mankind's ability to clone adult mammals.
- A revolution in the discovery of novel drugs and vaccines, driven by combinatorial chemistry.
- Transplants and implants, fueled by tissue re-engineering.
- Integrated computer technology.
- Alternative medicine and the role of faith in healing.

Force #1: Advances in Genetics

Mr. Dwyer predicted that the Human Genome Project will have profound implications on the nation's health care system. This $3 billion federally funded project will first target the three to four percent of genes that, if inherited, cause a disorder. The ultimate goal is to replace these genes and thus avert disease altogether. Thanks in large part to this initiative, a variety of specific advances will one day help to eradicate a number of diseases, as outlined below:

- Therapies will allow the sprouting of new blood vessels that bypass existing vessels with blockages. This "bio-bypass, grow-your-own" approach could have profound benefits in terms of reducing the risk of adverse events such as stroke and acute cardiac events. It could also have dramatic implications for some cardiac-oriented hospitals that currently derive 50 percent or more of their revenues from interventional cardiology.
- Anti-angiogenesis will one day allow the treatment of blood vessel disorders in the brain through the threading

of a catheter that will deliver an agent which will melt the blood vessels, thus eliminating the need for surgery (and thus the cracking of the skull). This technology may create conflicts between radiologists and neurosurgeons.

- Diagnostic gene "chips" will provide a unique DNA profile giving patients their predisposed risk of certain diseases, as well as recommendations for the best strategies to reduce the risk and/or treat the onset of the disease. For example, an individual traveling to Africa could find out if he or she is predisposed to contracting malaria, and could also receive personalized recommendations (based on genetics) for how best to prevent and/or treat the disease. But this capability creates ethical issues, particularly surrounding who will have access to genetic information that might reveal that an individual is likely to become very ill or to die at a young age.
- Anti-aging treatments will become more commonplace, including the possibility that the loss of a particular enzyme, telomerase, could be reversed, thus slowing down the aging process.
- Gene therapy may, over time, become a more promising approach. For example, it could one day allow the replacement of the recently discovered gene that is responsible for insulin production in those individuals who lack it. That said, there appears to have been only one successful gene therapy trial out of the 400 attempted thus far. (The immune systems of two boys in Paris, France, were turned on, allowing them to leave their sterile environment in a plastic bubble.) And at least one trial ended in tragedy—an 18-year old liver patient died at the University of Pennsylvania, resulting in suspension of the trial and shutting down one of the leading human gene therapy trial programs in the country.

Force #2: Advances in Cloning

Along with advances in genetics, Mr. Dwyer predicts that the technology of cloning will continue to advance at a rapid pace. The field has already moved from the cloning of the first animal from an adult cell in 1996—a task declared impossible in 1985—to the cloning of 50 mice from a single adult mouse in 1998. A next logical step could be the cloning of man (or certain human tissues), although it is possible that some countries might ban such research. Nonetheless, Mr. Dwyer believes that the cloning of man will occur within his lifetime.

Force #3: Combinatorial Chemistry and the Creation of Novel Drugs/Vaccines

Mr. Dwyer expects rapid innovation in the creation of novel drugs, driven largely from the findings of the Human Genome Project and the results of a new process for discovering drugs—combinatorial chemistry. This approach has dramatically increased the speed and scope of drug discovery while simultaneously reducing its costs. For example, a chemist working for three months under the traditional process would produce an average of 12 new compounds. Under the new process, that same chemist working three months could produce 10,000 new compounds but rather than casting their nets so wide, these chemists will instead use the knowledge gained from genetics to target drugs at specific proteins and specific diseases and conditions. For example, researchers are currently working on a drug that might be able to "lock-up" and neutralize HIV before it gets into the immune system. In addition, because some individuals with a particular genetic make-up do not respond well to certain

medications, it will one day be possible to determine in advance whether a particular drug will work for a particular individual, and to adjust treatment accordingly.

Mr. Dwyer believes that the number of new drugs in development will double or triple within the next five to 10 years. He also expects that new delivery techniques—including greater reliance on inhalation and "needle-free" injections—will lead to more effective drugs. The net benefits include the following:

- Nutriceuticals—that is, food that also delivers drugs—will become more prevalent. For example, Monsanto has a rice product that provides insulin and Nestle has a yogurt that supports the immune system. Several companies are developing food products (e.g., margarine) that actually lower cholesterol.
- New drugs will continue to be developed from plant species. Today, 25 percent of major drugs come from about 40 plant species. For example, soy may be a promising source for new drugs. The Japanese eat much greater amounts of soy than do Americans and enjoy much lower rates of prostate and breast cancer. Soy is readily available in the United States, which produces 50 percent of the world's supply.
- Cows and other animals will become "drug factories" as the science of cloning merges with newly understood approaches to transgenic production of important human blood components, anti-infectives, and other medicinal products.

Mr. Dwyer also noted that the economics of new pharmaceuticals are quite attractive. For example:

- Estrogen therapy to prevent hip fractures from osteoporosis runs $3,000 for 15 years, compared to $41,000 for the hip surgery that such therapy could prevent.
- Treatment for ulcers runs less than $1,000 per year, as compared to $28,000 for surgery. The number of ulcer operations fell from over 100,000 to less than 20,000 in 10 years.
- Finally, protease inhibitors for AIDS, which can cost $16,000 per year, avoids the $100,000 expense of caring for a AIDS terminal patient in the hospital.

But Mr. Dwyer also sounded some cautionary notes. While new drugs will be available to treat a large number of diseases in the not-too-distant future, multi-drug resistance is on the rise, leading to an increase in the incidence of (and mortality from) infections, tuberculosis, nosocomial infections in the hospital, and even bubonic plague. One-third of the 50 million deaths around the world each year are due to infection. In fact, deaths due to infectious agents rose by 58 percent between 1980 and 1992. Tuberculosis could infect a billion people over the next 20 years.

The good news, however, is that work on a variety of new bioengineered vaccines—including vaccines for childhood ear infections, infant diarrhea, gastric ulcers, HIV, and chlamydia—may one day help to counter some of these disturbing trends. Scientists believe one day vaccines will be grown right in food products such as bananas, potatoes, and tomatoes, for as little as 10 cents a dose.

Force #4: Transplants and Implants

Mr. Dwyer expects tissue re-engineering to be the wave of the future for transplants and implants. Techniques will let the cell from bone marrow tissue be "morphed" into various tissues such as skin, bone, and cartilage, allowing the creation of new skin grafts and knee caps. He also envisions use of islet implants that make it possible for individuals with diabetes to avoid taking insulin externally. Finally, due to a rising demand for transplants and a growing waiting list for human organs, he predicts that the industry will turn to the transgenic pig to help save lives. While today pig's organs can be used to keep patients alive temporarily until a human organ is available, he envisions a day when there could be animal-to-human transplants.

Force #5: Information Technology

Within information technology, Mr. Dwyer expects the huge advances in telemedicine to continue, including some driven by bio-electronic computers that will use complex combinatorial analysis and pattern recognition. He envisions a future in which medical robotics technology is capable of providing the following:

- A "third arm" for surgeons.
- Microsurgical systems that allow for endoscopic CABG (coronary artery bypass graft) surgery through an incision smaller than a pencil.
- Voice-controlled operating room equipment that allows the surgeon to operate from a remote site.
- Artificial vision through implants into the brain that bypass the retina.
  This technique recently allowed a patient who had been blind for 30 years to "see" in gray images a two-inch letter from a distance of five feet.

Mr. Dwyer also believes that advances in information technology will provide patients with personal health training, video house calls, virtual support groups, and provider report cards.
Longer term, Mr. Dwyer predicts that the science of nanotechnology will one day allow scientists to build machines that will flow throughout the body and provide various services at the subcellular level, potentially even rebuilding cells from the inside so as to avoid invasive surgery. In fact, IBM already has developed technology that can control atoms that are only a nanometer high. (A cell is 1,000 nanometers wide.)

Force #6: Complementary Medicine and Faith Healing

Mr. Dwyer sees a more prominent role for complementary medicine. But on a cautionary note, he warned that the growing popularity of herbal medicine suggests the need for greater oversight. In fact, a recent study of different manufacturers of St. John's Wort found wide variations in the degree to which the stated ingredients were actually found in the pills. Physicians also need to be aware of the medicines that their patients are taking, since a number of over-the-counter products can cause complications in patients. For example, one herbal medicine that is suspected to be helpful in killing prostate cancer cells is also associated with blood clots.

Interestingly, in the midst of this high-technology revolution, there has been a rise in the appreciation for the role that faith and spirituality play in human healing. This revival is driven in part by scientific evidence that confirms the value of what many people have practiced for years. For example, a study of cardiac patients found that those who had prayers said for them had 10 percent fewer complications, even in instances when the patients did not know about the prayers.

What All This Means for the Future

Mr. Dwyer closed by offering some near- and long-term predictions.

The Near Term (6 to 15 Years)

Within the next 15 years, he expects that there could be breakthroughs that lead to a cure for many cancers. A top priority for the National Cancer Institute is to develop agents that can starve tumors of their blood supply. Mr. Dwyer views the war on cancer as being very different than in the past, and expects major research dollars to be allocated to curing the disease. He also predicts that biologic computers will be able to master thinking processes, such as playing chess well enough to defeat "Big Blue." And he sees environmental toxicity being controlled by bio-engineered agents and medicines.

The Long Term (100 Years)

Within 100 years, he envisions implantable chips that might be able to translate any language or maximize learning of language through identification of peak neuroperformance. He believes that the average life span of a human could hit 200 years within the next century. He predicts widespread use of small-scale molecular devices that are built one atom at a time.

But he also cautioned that this progress raises some very real ethical issues. For instance, with respect to cloning, is it really in a person's interest to be made in someone else's image? With respect to reversing aging, is it in society's interest to extend the life (and therefore the time spent on Medicare) of a 65-year old when over 40 million Americans are uninsured? And on a related note, Mr. Dwyer reminded us that there is a growing gap between the "haves" and the "have nots" with respect to access to basic services, including health care. Less than half of all humans have ever used a telephone and only half use electricity every day. Roughly one in nine have owned a car. This gap has huge implications and creates tremendous challenges for those interested in improving the quality of health care for everyone around the globe.

CHAPTER II:
THE HUMAN GENOME PROJECT AND ITS IMPACT ON MEDICINE

Francis S. Collins, MD, PhD, director of the National Human Genome Research Institute of the National Institutes of Health (NIH), built upon Mr. Dwyer's presentation by providing a more detailed description of the Human Genome Project (HGP) and its implications for the future of medicine. His presentation was divided into three parts:

- History and current status of HGP and how it will change the practice of medicine.
- Predictions for the next 20 to 30 years.
- A review of the ethical, legal, and social issues that are a part of this future.

Underlying Philosophy of HGP

The underlying philosophy of HGP was that virtually all disease—excluding trauma—has a genetic component. That said, the role of genetics varies from disease to disease. While cystic fibrosis is primarily a genetic disease, adult-onset diabetes, cancer, heart disease, and asthma tend to be caused by a relatively even mix of genetics and the environment. And even AIDS, which is caused by a virus, has a genetic component. In fact, researchers have found that one percent of Northern Europeans have a particular spelling of a gene that confers resistance to HIV infection.

Genetics affects everyone, as each individual has glitches and risks embedded in his or her genetic code. While not everyone wants to know this information—or will be able to act on it—the general consensus is that most individuals do desire such information so that they can take action to either prevent onset of a disease or to have it diagnosed and treated as early as possible.

The Early Years: Studying Model Organisms

Dr. Collins offered a brief history of HGP. When it was first suggested in 1985, many viewed the project as audacious, too expensive, and virtually impossible to complete. Some found the subject matter to be boring, and consequently felt that the effort would attract mediocre talent. After vigorous debate on the merits of the project in the late 1980s, the United States Congress authorized the HGP in 1990 as a pilot involving NIH and other countries. The first major task involved studying model organisms, as the human genome was regarded as being too complicated to study without first understanding simpler species.

The End of the Beginning: Sequencing Human DNA

Human DNA is both simple and elegant, involving three billion letters of genetic code. Sequencing this code using technologies applied to and knowledge learned from simpler organisms proved to be quite a challenge. By March 1999, researchers had sequenced only 15 percent of the human genome. At this time the leaders of the 16 centers that are part of HGP got together and agreed to do whatever it would take to finish the sequencing by June 2000. Reaching this goal necessitated a ten-fold increase in capacity, as completion required the discovery of roughly 1,000 letters of DNA code every second of every day for 15 months. All of this work took place within the public domain, with sequences placed on the World Wide Web every 24 hours.

By the time the deadline arrived, a complete working draft of the human genome had been accomplished. It was released at a joint news conference with Celera Genomics, a private company that drafted its own version. Interestingly, the complete genome consists of roughly 40,000 genes, only 40 to 50 percent of what many researchers expected to find. (In fact, from a genetic perspective, humans are only twice as complicated as a round worm. That has 19,000 genes)

Identifying Disease-Causing Variations in Genes

The completion of the sequencing of the human genome marks the end of the beginning phase of the work of the HGP. As Dr. Collins noted, the genetic sequence represents a relatively modest accomplishment; it serves as the building block for the more ambitious task of trying to identify genes that cause specific diseases, with the goal of developing interventions to prevent and/or treat them more effectively.

The bulk of the effort during the current phase centers around studying variations in human genetics. Within the three billion base pairs of DNA that make up human genes, there are roughly 10,000,000 common variations, 200,000 of which have a functional significance. And only a small fraction of these are medically important. Finding these important variations requires the building of a catalogue that documents each of these 10,000,000 "spelling errors" (known as single nucleotide polymorphisms or SNPs). Then researchers must check them one at a time to determine if they are significant.

A successful public-private partnership that includes 10 pharmaceutical companies and the Wellcome Trust has been working since the end of 1998 on building this catalogue. The number of identified variations has grown dramatically, from just over 200,000 in January 2000 to nearly 1,500,000 by September of the same year. Nearly 3,000,000 SNPs will be identified by January 2001. All of this information is being placed in the public domain, as private sector interests view the information to be in the "pre-competitive" phase.

This effort is already beginning to pay dividends. Within the past two years, approximately three dozen disease-causing genes have been identified. For example, a gene associated with adult-onset diabetes was discovered in October 2000, much to the surprise of researchers who did not suspect that this particular gene had anything to do with the disease. Similar discoveries for many other diseases should occur within the next few years.

Next Step: Finding Ways to Help Individuals with Genetic Variations

Once SNPs that are associated with disease have been identified, private and public sector organizations can work to develop diagnostic tools to determine who is at risk, as well as new, more effective drugs, therapies, or other interventions to prevent and/or treat the disease. Dr. Collins laid out a three-pronged approach to the process that occurs after a gene is identified as being associated with a disease:

- Development of diagnostic tools to determine who is at risk, and preventive medicines or pharmacogenomics to prevent or treat the disease.

- Development of gene therapies that work to correct the gene itself.
- Understanding of the basic biological defect that causes the variation, followed by the development of drug therapy to correct this defect.

As an example of this first approach, Dr. Collins noted that roughly one in 300 individuals suffer from hemochromatosis, an easily treatable problem that causes excessive absorption of iron in the gastrointestinal tract, potentially leading to cirrhosis, heart failure, diabetes, and arthritis. Physicians often fail to diagnose the ailment. But thanks to discovery of the genetic variation that causes it, a screening test can now identify individuals with the variation. Similar approaches have also been used to increase screening rates in individuals with genetic variations that place them at higher risk for colon and prostate cancer.

Dr. Collins also provided an example of pharmacogenomics. By testing the impact of a drug that helps with narrowing of the arteries on individuals with different genotypes, researchers have determined that some patients with a specific genotype derive little or no benefit from the drug. As a result, physicians need not prescribe the drug to these individuals, and can instead look to other therapies that might prove more effective given their particular genetic make-up.

Even more important than the development of diagnostic tests and pharmacogenomic drugs is the ability to understand the basic biological defects that cause disease, and to come up with targeted drug therapies to address them. For example, researchers discovered that a particular type of leukemia is linked to breaks that occur in two specific genes. These broken-apart genes fuse together, causing the development of a form of chronic leukemia. The researchers also found the proteins responsible for this process. Using this information, investigators at Novartis have been able to design a drug that can block the fusion from occurring, thus preventing onset of the disease. During the initial trial of this drug, 31 out of the first 34 patients went into remission. Dr. Collins cites this as an example of "designer" drugs based on a molecular understanding of the disease. Dr. Collins expects the effort to understand genetic variations to take 10 to 20 years to complete. At the same time this work is going on, HGP will be actively engaged in other initiatives to understand what the genetic sequence means, including the following:

- Gaining a full understanding of the proteins within a cell.
- Understanding how genes turn "on and off" in carefully controlled ways.
- Comparing the human genome to that of a mouse, so as to understand where humans fit into life.

Ethical, Social, and Legal Implications

Examining the ethical, social, and legal implications of genetics is an integral part of HGP. In fact, the project sets aside five percent of its budget to study these issues. As a result, a growing body of literature is emerging. But while some policy decisions have been made, much more work lies ahead. Dr. Collins laid out six critical questions to be answered:

- Will effective legislative solutions to genetic discrimination be found?

  The biggest concern is the potential to lose a job or insurance coverage because of a discovery made about an

individual's genetic make-up. While roughly two dozen states have begun to address this issue, federal legislation is needed. A number of bills have been introduced into Congress, but none have been signed into law. Dr. Collins believes that a proposal sponsored by Senator Daschle, South Dakota (D), is the most carefully crafted legislation currently being considered. Dr. Collins urged passage of "preventive legislation" before widespread use of genetic testing leads to a crisis situation.

- Will we successfully shepherd new genetic tests from research into clinical practice? Who will decide what tests are used (e.g., the Food and Drug Administration, the marketplace, clinical guidelines)?
  An advisory committee to the Department of Health and Human Services is currently working on this issue. Because these tests often do not save money in the short term, the marketplace may not do a good job in ensuring their appropriate use.
- Can health care providers and the public become genetically "literate" in time?
  Providers generally know very little about genetics, yet they are the individuals responsible for talking to patients. Given that there are only about 1,000 genetic counselors in the entire country, many more providers (especially nurses) need to be educated about genetics, including how to convey risks to patients in an appropriate manner. Much work also remains with respect to the difficult task of educating the public. Without such education, a potential backlash against genetics could emerge. Fortunately, a collaboration of 120 organizations is presently involved in an ambitious agenda to move education forward in the provider community. NIH is also releasing an educational kit aimed at high school students; this interactive CD-ROM will be available to every high school biology teacher by Spring 2001.
- Will the benefits of advances in genetics only be available to a privileged few?
  Dr. Collins warned the industry not to create further separation between the "haves" and the "have nots."
- Will we arrive at a consensus about the limits of genetic technology for trait enhancement?
  Within the next 10 to 20 years, technology will allow the selection of traits for the next generation.
- Will we succumb to genetic determinism (i.e., the belief that genetics causes everything)?
  Dr. Collins reminded the audience that in the debate about "nature versus nurture," much of an individual's characteristics are still the result of the environment and expression of free will. Learning more about the "nature" side of the equation has not diminished the role of nurturing.

Predictions for the Future

Dr. Collins concluded his presentation with predictions for the next 30 years.

By the Year 2010

Within the next decade, Dr. Collins predicts the following:

- Predictive genetic tests will exist for 10 conditions, along with interventional therapies to address several of these conditions.
- Successful gene therapies will be available for a few conditions (but gene therapy will by no means be a panacea).
- Primary care providers will begin to offer genetic counseling.

- Pre-implantation diagnosis and selection of traits and characteristics will become available, with the limits of such technologies widely and fiercely debated.
- Effective legislation for dealing with genetic discrimination and privacy of information will be in place in the United States.
- Inequitable access to genetic technologies will still be the norm, especially in the developing world.

By the Year 2020

By 2020, Dr. Collins predicts the following:

- Gene-based designer drugs will be available for diabetes, hypertension, and many other disorders.
- Cancer therapy will be precisely targeted to the molecular fingerprint of a particular tumor.
- Pharmacogenomics will be established as a standard approach to treatment and drug therapy, with patient genotypes routinely considered in determining appropriate treatments.
- There will be a transformation in the diagnosis of mental illness, along with new therapies and shifting societal views (i.e., less of a blame-the-victim mentality).
- The industry will have perfected the ability to fix a single line of genetic code (e.g., "germline" gene therapy) without "messing up" the rest of the code.

By the Year 2030

Within 30 years, Dr. Collins expects the following:

- Comprehensive, genomics-based health care will become the norm, with individualized preventive medicine available. Illnesses will be detected by early, molecular surveillance.
- Gene therapy and gene-based drug therapies will be available for many diseases.
- A full computer model of human cells will replace many laboratory experiments.
- The average life span will reach 90 years, placing further socioeconomic strains on the nation.
- Major anti-technology movements will be active in the United States and elsewhere.
- Serious debate will be underway with respect to the possibility that humans will take control of their own evolution by going beyond disease to actually improving genetic traits.

Dr. Collins noted that mankind's history with respect to this issue is not a pleasant one. The only "antidote" is to ensure widespread education on the topic and to be honest and open about what is being attempted, so that limits can be placed. Society must be willing to make a collective decision not to pursue certain aspects, even if they are technologically feasible.

"We must never cease from exploration. And the end of our exploring will be to arrive where we began and to know the place for the first time."

—T.S. Eliot

CHAPTER III:
BREAKTHROUGH TECHNOLOGIES FOR THE NEW MILLENNIUM

Much of the remainder of the conference focused on how public and private organizations have been developing products and services based on advances in the understanding of genetics and other issues. These innovations represent the true benefit that initiatives such as the HGP are bringing to health care, as these products and services are on the "front line" of medicine, resulting in significant improvements in the quality of care for patients around the world.

A View from the Pharmaceutical Industry

George Morstyn, MD, senior vice president for development and chief medical officer at AMGEN, Inc., offered the perspective of the pharmaceutical industry. The world's largest independent biotechnology company, AMGEN strives to be the best human therapeutics company in the world.

In Need of a New Approach to Drug Development

Dr. Morstyn believes that the pharmaceutical industry is in need of a new approach to drug development. To support this view, he highlighted statistics that demonstrate the remote chance that research will result in a new drug reaching the marketplace, let alone becoming commercially successful. Less than two percent of research results in the development of a drug, with only 10 percent to 20 percent of these potential drugs ever gaining approval. And less than half of approved drugs end up being commercial successes. With many billions of dollars being invested in drug research, it is no wonder that successful drugs are so expensive. In addition, the total time to develop a drug—from synthesis to approval—has increased from roughly eight years in the 1960s to nearly 15 years today. (This is in spite of the fact that average time to gain FDA approval has fallen by over six months in the last few years.) Much of the increase is due to additional time spent in the pre-clinical and clinical trial phases. Not surprisingly, as the time needed to bring a drug to market has increased, so too have the total costs of development. In addition, some drugs have been withdrawn from the market once side effects were more fully understood. Each of these factors—low success rates, added time and costs, and product withdrawals—has become a "mountain" that pharmaceutical companies must climb in order to compete successfully.

Biotechnology to the Rescue

Dr. Morstyn believes that biotechnology can help to make these "mountains" less of an obstacle to success. With total product sales growing from $5.8 billion to $7.9 billion between 1997 and 1999, and with market capitalization tripling (from $61 billion to $190 billion) during this same time period, the biotechnology industry appears poised to have a dramatic impact on the quality of health care.

The Principal Advantages of Pharmacogenomics

Dr. Morstyn is particularly optimistic about the ability of pharmacogenomics to solve some of the challenges facing the industry. In his view, this approach offers the following advantages:

- More precise definition of diseases.
- Accelerated drug discovery.
- Improved tolerability, as potential interactions can be identified upfront.
  Pharmacogenomic approaches can help to reduce side effects before approval, thus minimizing the likelihood that a product will need to be withdrawn from the market.
- Increased efficiency of clinical trials, as drugs can be tested on smaller cohorts.
  This benefit is particularly important, as clinical testing has become a major "chokepoint" in the drug development process. As new technologies have allowed the industry to simultaneously tackle more diseases through the development of multiple compounds, finding adequate numbers of animal and human subjects for testing has become quite a challenge. More targeted medicines.

The Impact of Genetics on Health Care

The benefits of genetics on the field of health care go beyond those offered by pharmacogenomics. In Dr. Morstyn's view, genetics helps to transform the industry in the following ways:

- Diagnosis based on symptoms and testing will give way to prognosis, where disease can be predicted based on genetics.
- Guidelines and formularies that are used uniformly to treat all patients with a particular disease will be replaced by targeted therapies based on the specific needs of an individual patient, as determined by his or her genetic make-up.

- Standardized care, where patients are treated uniformly, will give way to tailored care.
- Universal blockbuster drugs that treat an entire class of patients will give way to "minibusters" developed with the aid of pharmacogenomics (an approach that should keep development costs relatively low).

"The first generation of research, which started about 100 years ago, was based on chemistry and serendipity. The second generation, started in the 1950s, has been based on biology and empiricism. The third generation is driven by skilled professionals using genetics, robotics, and information."

—Scrip Magazine, 1998.

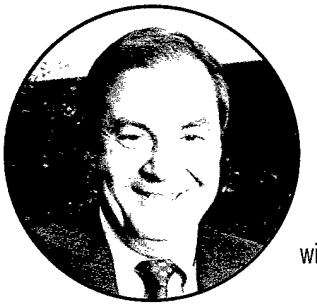
AMGEN's Role

Protein engineering, molecular biology, and cellular biology are at the core of AMGEN's competencies. Protein modification, in particular, has given the company new opportunities to take existing drugs and modify them. One example of this approach can be found in a potential drug to help patients with chronic renal insufficiency. Anemia associated with kidney failure represents a hidden epidemic in this country, as only about one in four (90,000 out of 350,000) anemic patients are treated. Other successes at AMGEN include the following:

- The discovery of the OPG gene and its role in osteoporosis.
  This discovery may allow the development of specific treatments that have few side effects. Other treatments may help to reduce the spread of cancer into the bone and reduce the effects of osteoporosis.
- The discovery of a new drug target linked to a small molecule linked to Alzheimer's disease (involved in the deposition of plaque on the brain).
  AMGEN is developing small molecules to delay and slow this process, thus postponing onset of the disease.

A View from the Provider Industry

Edward Eckenhoff, president and CEO of the National Rehabilitation Hospital (NRH) in Washington, DC, offered his views on how bio-medical technology is leading to breakthroughs in the provider industry, particularly with respect to rehabilitation. From his position as head of a specialty hospital system with a large research component in assistive technology and rehabilitative engineering, he envisions exciting new developments for the approximately 48,000,000 people in the United States who are disabled. New technologies are making everyday life easier for these individuals.



Six Themes with Respect to Assistive Technology

Mr. Eckenhoff laid out six themes that define the trends in assistive technology for individuals with disabilities.

Theme #1: Robots find a home in rehabilitation.

Before the advent of robots, animals were often used to help individuals with disabilities. Today, robotic technologies can help in a number of capacities, as outlined below:

- Assistive robots perform functions that assist humans, such as the dispensing of medications.

- Wearable robotics can help individuals to regain arm function, including assisting with movement of the elbow and grasping through use of a powered elbow and prostheses. Mr. Eckenhoff noted that while these types of devices can cost up to $60,000, they are often covered by insurance policies.
- Robotic wheelchairs are currently in development (one is awaiting FDA approval) that can help individuals to get around more easily on their own, including going up and down stairs.
- Robots can assist with physical therapy regimens by helping to move a patient's arm, or by nudging a limb toward the desired path during voluntary movement.

Many of these technologies, moreover, are surprisingly affordable.

"The role of new technology for individuals with disabilities is to add life to years, not necessarily years to life."

—Edward Eckenhoff

Theme #2: Rehabilitation is going wireless (along with everything else).

Remote-control devices and other similar technologies can help individuals with disabilities to perform tasks such as turning on and off lights, locking doors, and answering telephones. New "smart homes" are being built with appliances throughout the house that support individuals with disabilities in their daily activities. They keep track of the individual and even interact with each other. These appliances are capable of understanding a patient's baseline capacity, working with that patient to improve, and measuring progress against that baseline. For example, NRH has developed a mock home and village that can capture objective performance information.

Theme #3: Telehealth technologies come to rehabilitation.

The expansion of telehealth technologies has become very important to individuals with disabilities, who often find it difficult to get to their medical appointments. Technologies such as video meetings, digital medical records, and home health monitors and sensors (e.g., for blood pressure, pulse, body weight) have come to rehabilitation. Many of these technologies are inexpensive as they rely on POTS (plain-old-telephone system) and/or Internet-based systems to allow a video meeting between patient and provider. Some more expensive versions rely on professional telehealth systems and/or digital systems that provide more detailed information, including imaging and digitized medical records. For example, Kaiser Permanente has piloted a tele-home health project that takes advantage of home sensors that monitor blood pressure, pulse, blood oxygen, body weight, and glucose levels. The next step in this evolution is the development of wearable health sensors; examples include a "biopack" (being developed at the Massachusetts Institute of Technology) that can be worn around the chest and a ring (being developed by the University of Tennessee at Knoxville) that serves as a pulse oximeter. NRH has developed several technologies in this area, including the Interactive Rollabout Image Station (IRIS) and the Remote Interactive Touchscreen Assessment (RITA), both of which facilitate real-time video, voice, and touchscreen communication between patient and provider.

Theme #4: Rehabilitation and independent living find support in electronic health.

Web sites with medical information have become easily accessible to individuals with disabilities. Sites such as Koop.com, WebMD.com, and RehabManager.com could help to change the behavior of patients and service providers. NRH is developing its own offering (NRHHealthtown.com), an interactive site that allows patients in their homes to access information and to directly contact their providers.

Theme #5: Composite materials are showing up in rehabilitation products.

A number of new products (e.g., prostheses, leg braces) take advantage of lighter composite materials, making them much easier for patients to use. These products help to make individuals with disabilities feel like athletes again. Examples include the following:

- Ultralight leg braces featuring composites and titanium joints.
  These braces provide 1.6 times the strength of traditional steel braces and weigh half the steel brace weight.
- Racing chairs with carbon composite wheels.
- Advanced composite prostheses.

Theme #6: Functional electrical stimulation (FES) makes it into clinical practice.

FES can help patients in a variety of ways, as outlined below:

- FES can help to improve a patient's grasp.
  For example, an FES hand grasp system being developed at Case Western Reserve University uses implanted and external components, both linked to a laptop computer, to assist with grasp.
- FES can help to improve urinary control.
  For example, Medtronic has developed a system for urinary continence.
- FES can support improved gait and standing.
  For example, research and development from Free University in Berlin has found that electrical stimulation of leg muscles can help to produce useful function for people with paraplegia.

Summary and Looking Ahead

Mr. Eckenhoff believes that complex technologies are making life significantly easier for people with disabilities while simultaneously helping them to improve functionality. These same technologies can also make life easier for providers who can communicate with and monitor at-home patients from their offices. And as prices continue to drop, many of these technologies are becoming surprisingly affordable.

Looking ahead, Mr. Eckenhoff sees great promise in technologies being developed by the National Aeronautics and Space Administration (NASA), including virtual reality, computer modeling techniques, and human interface design (e.g., "joystick" car controls that can help to capture hand function). Using his crystal ball, he envisions a day in which technologies such as heads-up displays and wearable computers serve to enhance reality while EEG processing may provide output from people who are "locked in".

A View from NASA

Arnauld E. Nicogossian, MD, the chief health and medical officer for NASA, reviewed how breakthroughs in bio-medical technology at the agency are having an impact on the quality of health care, both in outer space and on earth. He began by emphasizing the need for the field of medicine to bring the physical and biological sciences together. (NASA recently created a single office that combines these areas.) He also cautioned that because technology can impact human adaptation to the environment, researchers must examine and understand both the good and bad aspects of these innovations.

The Goal of NASA Health Care: Safeguarding Crews in Unique Environments

NASA's primary goal with respect to health care is to maximize the safety, health, and productivity of the agency's workforce, taking into account the unique health care requirements created by space travel. NASA must provide for healthy crews, maintain health and well-being during the mission, and ensure rapid re-adaptation to gravitational forces, following return to earth.

NASA missions are often characterized by exposure to radiation, extended periods of isolation, living in micro-gravity, and rapid re-entry into the earth's atmosphere and gravity. The human body experiences numerous changes during these missions, including the following:

- Neurovestibular disturbances.
- Cardiac deconditioning, including alterations in blood pressure and blood volume/fluid.
- Decreased immune function.

  Several studies have documented a loss of immune response among people who travel in space. This is a result of a loss of gravity as well as the isolation and confinement that characterizes the environment. Similar types of problems can exist in people (especially the elderly) who find themselves confined to their homes.
- Variations in the endocrine (or nervous) system.
- Muscle atrophy.
- Disuse osteoporosis, or the loss of bone mass.

  Dr. Nicogossian noted that there are parallels between space flight and aging. In essence, space flight results in an accelerated aging process. But unlike on earth, this process is reversible and not associated with chronic and debilitating illnesses.

Achieving This Goal

In many ways, humans traveling in space become "unfit to function on earth." Just as assistive and rehabilitative technology assists individuals with disabilities on earth, a variety of strategies and technologies are needed to help humans cope with the disabilities created by space. To that end, NASA maintains the health, safety, and productivity of its crews in a variety of ways, as outlined below.

Selection and Training of Crews, State-of-the-Art Spacecraft

NASA uses stringent criteria in selecting crews, and then limits contact with these crews immediately before the mission. It also conducts extensive training to allow crews to function effectively. Equally importantly, NASA builds state-of-the-art spacecraft. In developing these complex machines that are made up of inter-related systems, NASA engineers translate function, and performance into vehicle design, with an eye towards the needs of humans. This approach leads to a much better system in terms of ergonomics.

Designing with an Eye Towards the Needs of Humans

Dr. Nicogossian recommended that other manufacturers follow NASA's lead in emphasizing the needs of humans in designing new products. Automobile manufacturers appear to have learned this lesson, as they now make cars from the passenger's perspective. Designers of homes and workplaces must also learn to build from the perspective of those who will live and work in their creations.

In building the spacecraft, NASA personnel must also be mindful of the time and distance parameters that exist in space, as these have tremendous implications for telemedicine and telecommunications systems. While communication from the Earth to the Moon takes only 1.5 seconds, sending and receiving signals to and from other planets can take anywhere from 2-15 minutes (for Venus) to 320-337 minutes (for Pluto).

The Current Protocol for Crews

NASA currently provides health care services to its crews before, during, and after flights, as indicated below:

- Pre-flight: annual evaluations, preventive care, and monitoring.
- In-flight: a daily personal medical conference, periodic health and environmental monitoring (also conducted during critical mission operations), an on-board medical and environmental monitoring capacity, and health maintenance measures (with follow-up) as indicated.
- Post-flight: care and follow-up until recovery.

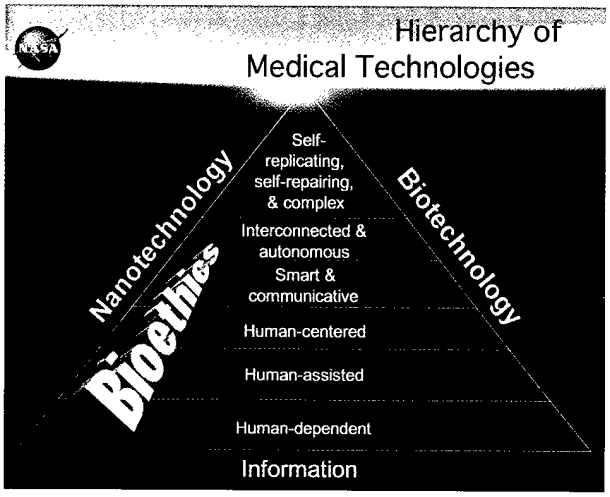
Future Requirements for Crews

Time, distance, and microgravity will create a unique set of requirements for future NASA health care systems, which need to be autonomous, minimally invasive, compact and portable, human-centered, and self-diagnosing/self-repairing. In fact, Dr. Nicogossian sees a shifting paradigm in the actions undertaken in caring for flight crews, as outlined below:

- The current preflight focus on preventive health care and medical intervention will be replaced by preventive screening and more advanced health maintenance.
- In-flight use of secondary prevention and countermeasures will give way to primary care that makes use of more effective monitoring and intervention.
- Post-flight care that previously consisted of tertiary and rehabilitation services will instead emphasize preventive care and health maintenance.
- Rather than focusing on the entire organism for intervention, only affected areas will be targeted, thus minimizing potential iatrogenic effects.

Cutting-Edge Technologies Critical to Meeting These Requirements

Cutting-edge technologies hold the key to meeting these future requirements. Dr. Nicogossian described a hierarchy of medical technologies that are applicable in space. These technologies (which combine information, biotechnology, and nanotechnology) range in sophistication, with some being dependent upon humans while others are complex, autonomous, self-replicating, and self-repairing systems.



Courtesy of NASA

A handful of these technologies are described below:

- Biologically-inspired technology takes design principles from living systems and translates them into autonomous, anticipatory, collaborative, self-modeling, and self-repairing systems. Examples include artificial hair cell sensors and bio-molecular motors.
- Medical informatics integrates telecommunications, medical information, and technology to enhance health care in remote locations. For example, the telemedicine instrumentation pack or TIP consists of a comprehensive suite of compact and portable equipment for diagnosis and communications. Another technology—the range-of-motion suit and smart shirt—remotely monitors the user's positions, movements, and health data.
- Advance human-machine interface technology provides heads-up monitoring, inspection, inventory, and remote monitoring capabilities, along with hands-free access to information. Examples include the human-centered wireless augmented reality prototype (WARP) that provides hands-free access to data and communications, and biosensors, which allow compact, minimally invasive monitoring of internal body parameters.
- Immersive environments, such as virtual reality and haptic systems, allow users to see, feel, and move remotely located objects. For example, MEMICA allows the wearer to feel "force" and "stiffness" of remotely located objects or objects in environments hostile to human life. Another example is virtual, three-dimensional modeling, which lets the user practice skills or plan methods to reduce the invasiveness of a surgical procedure.
- Noninvasive procedures accommodate mass and size constraints in space flight. Examples include ultrasound (externally applied sound waves that break up blood clots and other masses), keyhole surgery that requires only a small incision, and nanotechnology (microscopic machines that directly repair the affected area via an injection).

- Advanced imaging technologies provide noninvasive diagnostic capabilities while also enabling the long-range search for life on other worlds. Examples include high-resolution imaging that can detect and autonomously react to faint signs of life on distant planets, and reconstruction of serial sections (ROSS), which uses noninvasive, high-resolution MRI imaging for the detection of breast cancer.

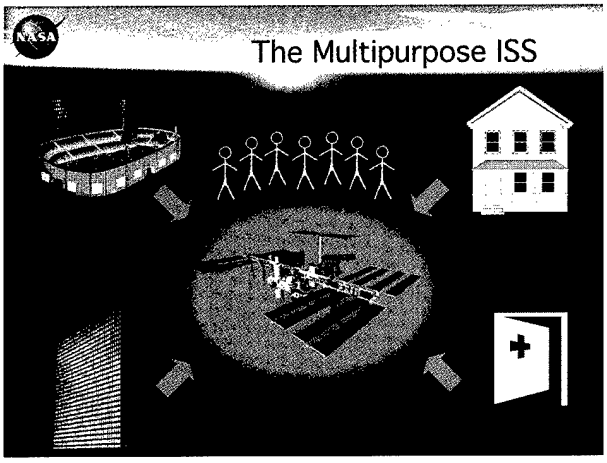
Applications on Earth

Many of these technologies have applications on earth. For example:

- Medical informatics can play an important role in home health care. Technologies designed to deal with the isolation of crew members in space can also serve home-bound patients.
- Technologies designed for immersive environments can help with "virtual" pre-surgical planning.
- Human-machine interface technology can assist with fetal monitoring, and to help patients confined to bed rest and/or home.
- Advanced imaging technologies can aid in the early detection of cancerous tumors and other diseases.
- Nanotechnology can allow for noninvasive treatment and care.

The Next Frontier: A Multipurpose International Space Station

According to Dr. Nicogossian, the next vehicle for helping NASA to meet its goal of developing a healthy, safe, and productive living/travel in space is the multipurpose international space station (ISS). It is the next platform for NASA to study how people can live more productively and safely in space. The ISS will allow NASA to learn how to sense the environment so as to avoid problems or emergencies. Dr. Nicogossian expects that findings from the ISS should also have relevance on Earth, especially for learning about how to help the elderly—who are often home bound—stay healthy and productive.



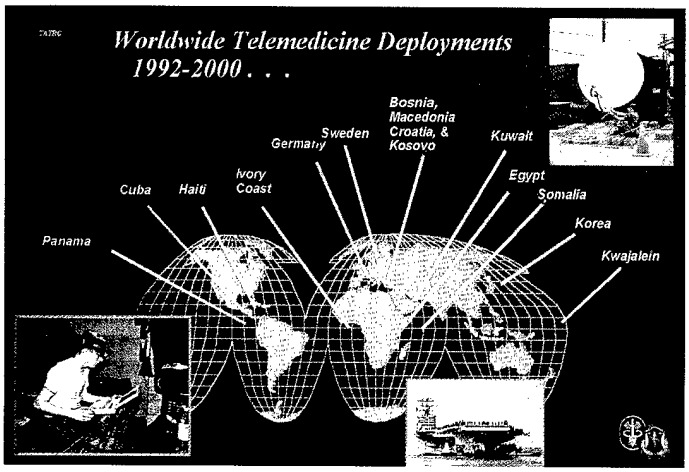
Courtesy of NASA

"Space medicine of today, combined with tomorrow's medical technology, will allow NASA to send humans to explore the solar system and to improve the quality of life on Earth."

—Arnauld E. Nicogossian, MD

A View from the Military

Gary Gilbert, PhD, special assistant for information sciences at the Telemedicine Advanced Technology Research Center (TATRC) of the Army Medical Research and Materiel Command, highlighted the role of telemedicine and medical informatics in the US military. He began by noting that telemedicine and informatics, like research on the human genome, is at the "end of the beginning" phase of evolution. Telemedicine began in the Army in 1992; the basic idea was to provide a medical telepresence that could support specialty care in far-flung, difficult-to-serve regions. Today, telemedicine is deployed by the US military in regions throughout the world.



Courtesy of TATRC

Telemedicine and Informatics to Support Operations in Bosnia

Perhaps the best recent example of the Army's use of telemedicine and informatics came in support of the military offensive in Bosnia, where these types of technologies supported facilities in Bosnia and Hungary with capacity for up to 170 beds, 400 sick calls or clinic visits per day, 200 X-ray exams, and up to 25 CT studies per day. The key user requirements included patient accountability, minimizing evacuations, rapid response to trauma, specialty medical consultations, and medical situational awareness. The functional/technical capabilities deployed to meet these responsibilities included the following:

- Telemedicine imagery.
- Filmless teleradiology.
- Digital CT scanner and ultrasound.
- Tele-surgical mentoring.
- Hospital information system.
- Field medical and patient management information systems.

The evolution of satellite, voice, data, and video communication networks has led to these networks becoming smaller and smaller over time.

Even today, much of the telemedicine structure remains in Bosnia. In fact, it is growing, having spread to most of Europe. Some have criticized the military for spending so much on this network, but as Dr. Gilbert noted, it is often very difficult to take a new, popular technology away from physicians.

One of the critical issues facing the military with respect to telemedicine is whether to use real-time or "store-and-forward" modalities. The answer is driven by the type of information and presentation format that is needed for teleconsultations. The lesson from the Balkans is that the appropriate choice will depend upon the requirements and capabilities at the delivery site. Modality requirements vary by types of consultations, the echelon of care, and the mission being supported. Capability to deliver varies according to equipment, bandwidth, training, and technical support available at the delivery site.

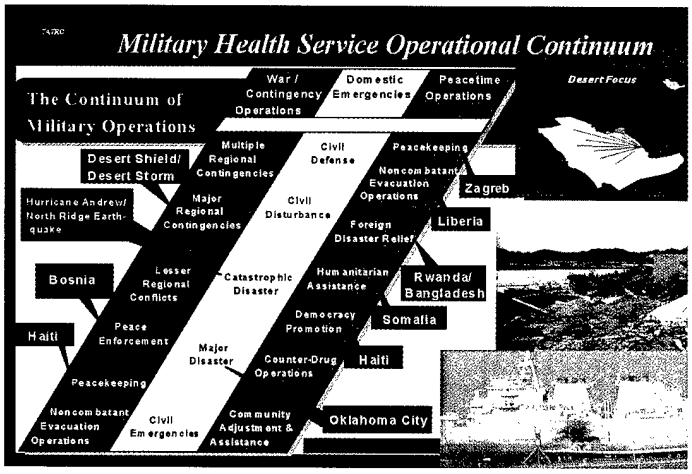
The classic view of telemedicine is real-time consultations in which consulting physicians directly interact with patients and/or other health care practitioners. In Bosnia, this type of real-time capability was available for radiology (e.g., real-time ultrasound), distance learning (e.g., grand rounds from major academic medical centers), and telesurgical applications, including telementoring via laparoscopic video and video teleconferencing and telepresent surgery via a robotic arm. But because there were so few casualties in Bosnia, there is no way to know whether these telesurgical technologies were in fact effective.

The "store-and-forward" approach was utilized by the Navy in Bosnia, since real-time videoconferencing was found to take up too much bandwidth. The Navy instead turned to a system in which medical records were forwarded (with or without still image and/or audio attachments) via e-mail, the Internet, or fax. Similarly, the Armed Forces Institute of Pathology and dental professionals turned to a web-based approach for their telemedicine applications.

In some instances, use of both real-time and store-and-forward approaches make sense. For example, information (e.g., imaging) on a patient can be stored and forwarded to a medical consultant, who can then use real-time teleconferencing to discuss the appropriate course of action with the patient and his or her caregivers.

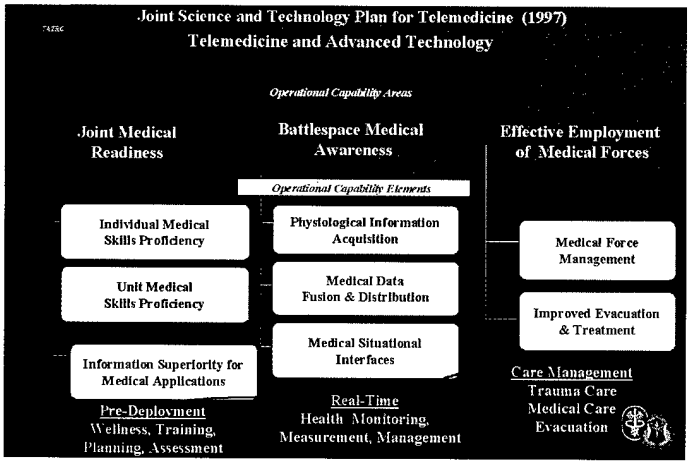
Telemedicine in the Post-Bosnia Era

Dr. Gilbert sees a role for telemedicine in the full continuum of military operations, including times of war, domestic emergencies (e.g., hurricane relief), and peacetime operations.



Courtesy of TATRC

He sees an expanded definition of telemedicine that utilizes the technology around the world for all three types of activities. The current Joint Science and Technology Plan for Telemedicine (developed in 1997) divides telemedicine and advanced technology into three areas of operational capability—joint medical readiness, battlespace medical awareness, and effective employment of medical forces.



Courtesy of TATRC

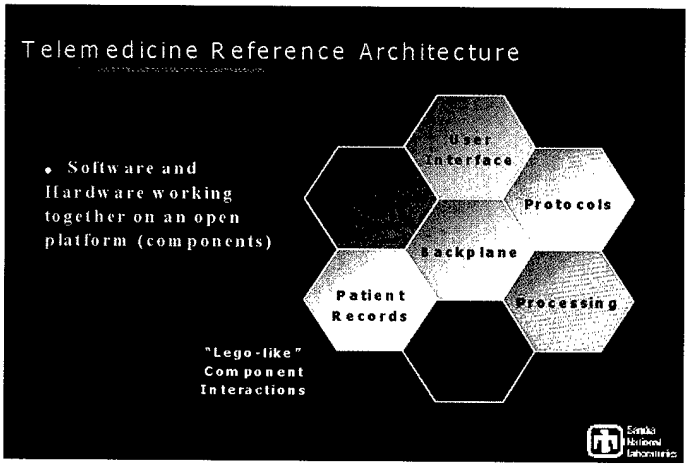
Dr. Gilbert provided examples of some of these types of projects, as outlined below:

- SMART, or Special Medical Augmentation Response Team: Medical command control and communications telemedicine requiring hardware, software, and communications interoperability standards.
  SMART was successfully deployed in disaster relief for Hurricane Mitch, in San Salvador during a natural disaster in December 1998, and at the Walter Reed and Eisenhower Army Medical Centers.
- Warrior Personal Status Monitor: A noninvasive patient assessment that can be transmitted to an individual patient's or medic's personal computer.
  Dr. Gilbert noted that there is a lot more work to be done with respect to this type of technology.
- Personal Information Carrier, or PIC: A successfully tested, field-deployable medical record that relies on voice recognition technology and has much more capacity than does smart-card technology.
- Virtual Retina Scanning Laser Image Display: A very small device that can display information to a soldier or medic without obstructing vision.
- Special Operations Forces (SF) Digitized Medical Handbook: A reference handbook on treating patients for individual medics or soldiers who for whatever reason cannot or should not communicate with others.
  Embedded functions include an electronic version of the SF Medical Handbook, an electronic medical record, an interactive medical reference library, clinical guidelines for "wilderness medicine," specialty medical knowledge, medical sustainment training, focused teleconsultation, and Internet access.
- Guidelines Interchange Format (GLIF) 3.0: A set of guidelines incorporated into the special operations notebook that helps to guide the patient and/or medic through the following: assessment, diagnosis, desired outcomes, intervention, and actual outcomes.
- Global Grid Telemedicine System: A system for providing centralized transparent network management and consult routing with automated expert system technology.
  This system leverages existing and available military telecommunications infrastructure backed up by civilian networks to provide remote military health care providers with telemedicine access to US-based medical centers.
- WIN-POC (Proof-of-Concept) Switch: A switch that enables use of a single piece of equipment to reach hospitals through any of a variety of communication channels (e.g., voice, the Internet).

The Future: A Wireless Medical Enterprise at the Point of Care

Dr. Gilbert concluded his presentation by highlighting the future of telemedicine and informatics within the military. He believes the next logical step is to give physicians tools that will allow better care management at the point of care. Through use of hand-held devices and very small computers, physicians will be able to access at the point of care a patient's computerized medical record, administrative support, research support, and evidence-based guidelines. They will also be able to access the Internet and to send and receive images. In short, these technologies will support physicians at the point of care through a wireless medical enterprise.

Dr. Gilbert noted that a platform is needed that supports this type of system. To that end, the military is developing a "telemedicine reference architecture," a "lego-like" integration of interactive components that, through hardware and software, work together in an open platform.



Courtesy of TATRC

In addition to this effort, the military is also working on the following:

- Distributed computerized patient records via the web.
- Bringing standards to telemedicine (a collaborative effort with national organizations).
- PC-based learning and interactive training for medical personnel in the field.
- Medical robots, including intelligent medical robots (that go into combat situations and/or other dangerous situations) and aquatic/marine robots.

  The objective is to develop a system of robots that can take on more and more of the work.

The goal of all of these initiatives is to help to improve the quality of care delivered to military personnel while at the same time enhancing the safety of those providing the care.

CHAPTER IV:
HEALTH CARE AFTER THE INFORMATION AGE: THE BIO-INTELLIGENCE AGE

Richard Satava, MD, FACS, a professor of surgery at the Yale University School of Medicine, closed the conference by describing what he sees as the next era in health care—the "bio-intelligence age."

Information Age Already Firmly Entrenched in Health Care

He began by noting that the information age no longer represents the future of health care. Rather, it is firmly embedded in the present. For example:

- Small, hand-held devices now exist that allow portable ultrasounds. These machines, which cost less than $20,000, act as a "virtual stethoscope," letting physicians in an outpatient clinic look inside the body (e.g., to instantly identify if a patient has gallstones).
- Robotic surgery has been used since 1993, while telesurgery has been used since 1996. Twelve centers in Europe and the United States now conduct robotic heart surgery.

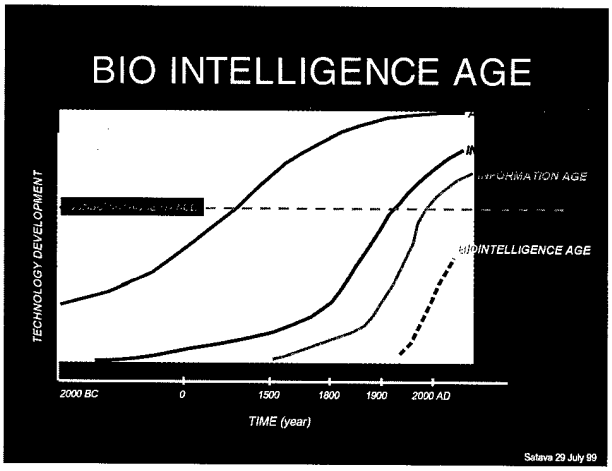
In Dr. Satava's view, the remainder of the information age will be characterized by relatively minor, non-disruptive technologies. Information represents a third domain (along with physical space and time) that must be treated as a solid object.

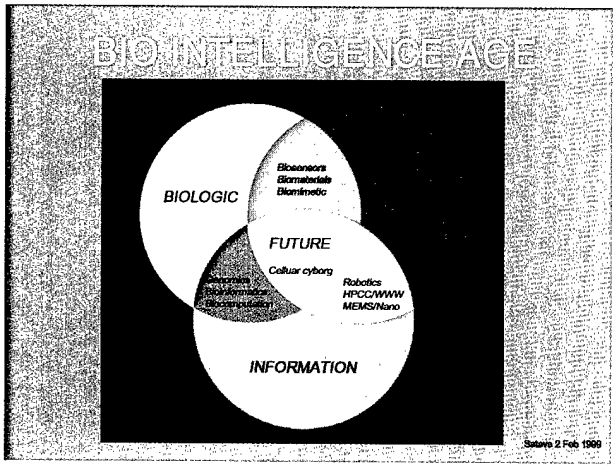
"The information age is NOT the future... the information age is the present."

—Richard Satava, MD, FACS

Next Frontier: The Bio-Intelligence Age

Dr. Satava sees science moving toward interdisciplinary fields that encompass all dimensions, including space, time, and information. He believes that the next frontier in medicine revolves around the Bio-Intelligence age, which will replace the information age that had its roots as far back as 1800. The roots of the bio-intelligence age go back to the mid-1900s; this age is characterized by the bringing together of research findings from the biological, physical, and information sciences. In the past, most new technologies were based on research that focused on only one of these three scientific disciplines. What is emerging now is interdisciplinary research that is occurring at the intersection of two of the sciences, as evidenced by the movement within academia, industry, and government laboratories to create new departments and divisions such as bioinformatics or biorobotics. For example, the fields of genomics, bioinformatics, and biocomputation combine findings from the biologic and information sciences, while robotic technologies, micro-electromechanical systems (MEMS), and nanotechnologies take advantage of knowledge learned in both the physical and information sciences. Similarly, technologies that rely on biosensors, DNA chips, biomaterials, and bio-mimetic systems are based on the combining of findings from both biologic and physical sciences.





Dr. Satava believes that the biggest payoffs are yet to come. The power of the future will occur where all three disciplines intersect, taking advantage of the biologic world, the physical world, and the information world. This next age of medical discovery will be based on a detailed understanding of biologic and physical processes, and supported by a whole host of smaller, cheaper, ubiquitous devices that use less power and are transparent to the user because they have local intelligence. The net result will be a "smarter" world, as networking (e.g., through informatics and telecommunications) provides for distributed or embedded intelligence that enables interaction between systems without human intervention. Just as a human need not think about breathing or walking, these local systems will have knowledge that is transparent to the user of the overall system. The next wave will be what is known as "Bio....X" in which biological processes are mimicked or otherwise incorporated.

The Impact of Bio-Intelligence on the Future of Medicine

The Bio-Intelligence Age will revolutionize the future of medicine. Dr. Satava envisions a business "medical ecosystem" fueled by new capabilities that drive the development of new devices and technologies in an upward spiral of growth. Dr. Satava highlighted the "five P's" that will characterize this era:

- Predictive medicine, based on genetics, yielding specific medications.
- Preventive medicine through proactive interventions.
- Point-of-care medicine in the home and workplace that takes advantage of mobile communications, ubiquitous computing, and local intelligence.
- Parametric medicine, where multiple parameters, over time, are referenced to a patient's own baseline and compared to a standard model.
- Personalized medicine, with individualized treatments for each patient.

In short, the field is at the beginning of a new era, characterized by multiple opportunities. Dr. Satava highlighted several of the major initiatives within the emerging field of Bio-Intelligence.

- Defense Advanced Research Projects Agency's (DARPA) Bio Futures Program, which focuses on the modeling of biologic behavior, biological computers, the language of biology, interfacing the biotic to abiotic world, mimicking the brain, biology on the move, and biomaterials.
- NASA's Astrobiology and Bio-astronautics Program.
- The National Cancer Institute and National Institutes of Health's Unconventional Innovations Program.
- The National Science Foundation's Nanotechnology Initiative.
- Stanford's Bio...X, which has received $150 million in seed money from Microsoft co-founder Paul Allen.

Examples of Bio-Intelligence Applications

To give a sense for the tremendous opportunities that this new era will create, Dr. Satava highlighted a handful of bio-intelligence applications that are currently under development:

- The placement of transmitters on bumble bees to identify and transmit the location of biologic agents (a war-time application that combines the biologic and physical world).
- Electrodes that record motion placed in cockroaches, enabling scientists to record & then interpret walking. Next, implanted electrodes will allow researchers to "drive" the insect, and direct the bugs to crawl under buildings to identify survivors of earthquakes, explosions, and other natural and manmade disasters.
- Transmitters placed through electrodes in the brains of moths whose antennae are receptive to compounds in land mines which then fly over suspected areas to identify the location of mines.
- Crab-like robots that can negotiate the surf.
- Microsurgical applications that allow operations on insects.
- Implantable drug-delivery systems placed on chips the size of a dime.
- Biomaterials that are ten times stronger and one-seventh the weight of titanium.
- Production of synthetic organs through use of tissue engineering.
  The first steps for producing a synthetic liver and artificial blood vessels have already been taken.

Future Vision for Bio-Intelligence: Building a Virtual Human

In Dr. Satava's view, the most important application of Bio-Intelligence is the creation of a Holographic Medical Equivalent Representation (HOLOMER)tm or "virtual human." Through CT or magnetic resonance imaging (MRI) technologies, physicians will one day be able to take a complete three-dimensional image of a human as part of an annual physical, at a cost of roughly $700. Multiple scans will be used to allow physicians to see greater detail in particular areas. These three-dimensional images, or HOLOMERS, will appear in the air in the physician's office, enabling both the patient and physician to view the internal anatomy of the patient in a non-invasive manner. The image will also contain the patient's medical records, vital signs, and laboratory data—each of which will be available simply by "clicking" on an organ.

The Virtual Human

These images will provide more than just information. Rather, they will assist in diagnosing and treating a patient. For example, physicians will be able to perform non-invasive, virtual colonoscopies, endoscopies, and other procedures to help diagnose cancers and other problems. If a problem is found and complicated surgery is required, physicians can first "practice" the surgery on an image identical to the patient. Post-surgery, a new scan can help to determine what difference the procedure made, thus providing real-time outcomes.

One day these images will even function as human surrogates that allow physicians to predict the impact of an intervention on a particular patient before actually using it. For example, medications could be administered to determine what effect they will have. And in an era where animal and human clinical trials often serve as a roadblock to the discovery of effective new medications, these human surrogates offer the potential to very quickly conduct thousands of simulated trials of a new drug. While these simulations cannot completely replace the need for animal and human trials, they can dramatically reduce the number of subjects needed.

Dr. Satava sees applications that go beyond health care into other sectors of the economy. For example, HOLMERS could be used by automobile manufacturers as virtual dummies in car crash tests. They can also be used by the clothing industry as virtual models to assist in the development of more customized clothing. In fact, there are very few parts of society that this technology would not touch.

Implications for Health Care

Dr. Satava highlighted the major implications of the Bio-Intelligence Age on the health care industry.

Practical Implications

He began with the practical implications that bio-intelligence will have on the field of medicine.

- Intra-disciplinary research will become more important, as the complexity of research will intensify.
- Devices and materials (e.g., networks, sensors) will mimic biological processes.
- Humans will be incorporating new devices.
- Artificial organs will be used in transplants.
- Life extension will result in an older population with more chronic disease.
  That said, Dr. Satava noted that there is no scientific evidence at this time that human life expectancy will go beyond 120 years, however research in apoptosis and teleromeies look promising.

Most importantly, perhaps, the cumulative impact of Bio-Intelligence could be to produce a paradigm change in which medicine is no longer primarily about treating disease, but rather about preventing it. To make this vision a reality, however, the medical community will have to adopt these new technologies. Compliance remains the number-one problem among both patients and providers. The good news is that many of these technologies are "passive" and therefore do not require patient acceptance. In addition, most new technologies come with training materials that will help providers feel more comfortable about using them.

Moral and Ethical Implications

Dr. Satava warned that the technological successes that he believes are possible will raise moral and ethical issues. For example:

- Should we do research in areas that we may not be able to control?
  Mankind may have the potential to develop intelligent machines, clones, nanobots, and other technologies that are as smart or smarter than humans. Researchers could conceivably end up creating something that humans are not able to control.
- Will prolonging life through technology result in more disease in the overall population?
- Can we change medicine from treatment to prevention of disease?
- In defeating diseases, will technology change humans into a combination of man and machine, perhaps altering what it means to be human?
- How will we decide who gets the technology, especially in third-world nations?

Any sufficiently advanced technology is indistinguishable from magic.

—Arthur C. Clarke

To deal with these issues, Dr. Satava urged the industry (especially physicians) to breathe morals and ethics into these research activities and the use of new technologies. Noting that technology itself is neither good nor evil, he called on the industry to place appropriate limits to ensure that these technologies are applied with compassion for the benefit of mankind.

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